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Ihre Zeichen und Nachrichten vom

July 25, 2005

Gesch.-Z.: Bitte bei Antwort angeben

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12.09.2005

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ICCVAM EXPERT PANEL REVIEW OF IN VITRO TEST METHODS FOR IDENTIFYING OCULAR CORROSIVES AND SEVERE IRRITANTS

Public comment concerning the *"Accuracy and Reliability Reanalysis Addendum"* - Executive Summary and Section IV: HET-CAM Test Method, dated 25 July 2005

Dear Dr. Stokes,

as you know I am serving as an expert for the IRE (Isolated Rabbit Eye) test on the ICCVAM expert panel of in vitro methods for identifying ocular corrosives and severe irritants and as a reviewer for the BCOP test.

To support the ICCVAM Expert Panel Review I have submitted several data sets for review that were generated in a national German validation study of the HET-CAM test.

Due to my involvement in organizing the *"5th World Congress on Alternatives and Animal Use in the Life Sciences"* that was held in Berlin two weeks ago, I have been able only the new IRE and BCOP data sufficiently but not the analysis of the HET-CAM data that we submitted.

However, after studying the HET-CAM BRD and taking into account my responsibility as principal investigator and author of several of the documents that I submitted to NICEATM, I want to comment on the reanalysis of the HET-CAM data, since some of the information that I provided is not documented appropriately both in the executive summary and in Section IV, which is covering the HET-CAM test. Moreover, in several instances the authors of SECTION IV do not refer to the correct literature or have ignored and not discussed important information published previously.

Taking into account the extensive biostatistical evaluation of the original validation study of the HET-CAM test in Germany (Spielmann et al., 1996), which was conducted in a joint national biostatistical project funded by the Federal German Minister for Research and Technology (BMBF) I want to ask you to provide the experts of NICEATM and the expert panel of the HET-CAM BRD with the enclosed information, which may help to better evaluate the HET-CAM documents that Dr. Manfred Liebsch and I have submitted.

Please excuse again that I did not manage to send our comments any earlier. I do however hope, that the expert panel will take our comments into account before finalizing the BRD and the *"Accuracy and Reliability Reanalysis Addendum"*.

With the best regards
Sincerely



Dr. med. Horst Spielmann
Direktor und Professor
Head of Dept. 3 "Scientific Services"
and Head of ZEBET

Enclosures: public comment with 5 attachments